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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,806	05/08/2006	Deepak Gandhi	077567-0018	6159
31824 7590 06/14/2010 MCDERMOTT WILL & EMERY LLP 18191 VON KARMAN AVE.			EXAM	INER
			STEWART, JASON-DENNIS NEILKEN	
SUITE 500 IRVINE, CA 9	02612-7108		ART UNIT	PAPER NUMBER
,,			3738	
			MAIL DATE	DELIVERY MODE
			06/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary Examiner

Application No.

10/578,806 GANDHI ET AL. Art Unit

Applicant(s)

earned patent term adjustment.	See 37 CFR 1.704(b).	
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		JASON-DENNIS STEWART	3738		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
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Status					
2a)□	Responsive to communication(s) filed on <u>15 Ja</u> This action is FINAL . 2b) This Since this application is in condition for allowar closed in accordance with the practice under <i>E</i>	action is non-final. nce except for formal matters, pro		e merits is	
Disposit	ion of Claims				
5)□ 6)⊠ 7)□	Claim(s) 1-14,18 and 40-50 is/are pending in the 4a) Of the above claim(s) is/are withdraw claim(s) is/are allowed. Claim(s) 1-14, 18 and 40-50 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or	vn from consideration.			
Applicati	ion Papers				
10)🛛	The specification is objected to by the Examine The drawing(s) filed on 15 <u>January 2010</u> is/are: Applicant may not request that any objection to the c Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	a)⊠ accepted or b)⊡ objected drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	a 37 CFR 1.85(a). jected to. See 37 C	FR 1.121(d).	
Priority ι	ınder 35 U.S.C. § 119				
a)	Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau.	s have been received. s have been received in Applicati ity documents have been receive I (PCT Rule 17.2(a)).	on No ed in this National	l Stage	
Attachmen	t(s)				
1) Notic	e of References Cited (PTO-892)	4) Interview Summary	(PTO-413)		

Attachment(s)		
Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413)	
Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date	
3) ☑ Information Disclosure Statement(s) (PTO/SB/08)	5) intotice of Informal Patent application	
Paper No(s)/Mail Date 23 February 2010.	6) Other:	

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DETAILED ACTION

The following is a Non-Final Office action in response to communications received on 1/15/2010. Claims 1 and 3 have been amended. Claims 4-8, 15, 16, and 19-39 have been cancelled. Claims 40-50 have been added. Therefore, Claims 1-3, 9-14, 17, 18, and 40-50 are currently pending and addressed below.

Oath/Declaration

The new oath/declaration filed 02/09/10 is accepted.

Drawings

1. The drawings were received on 01/15/10. These drawings are accepted.

Allowable Subject Matter

The indicated allowability of previously filed claims 5 and 6 is withdrawn in view
of the newly discovered reference(s) to Brazzle et al. and Speidel. Rejections based on
the newly cited reference(s) follow.

Response to Amendment

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The amendments to the claims are sufficient of overcome the 35 U.S.C. 112, 2nd paragraph rejections of the previous Office action.

Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be neadtived by the manner in which the invention was made.
- 4. Claims 1-3, 10, 13, 14, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer 2003/0009215 in view of Brazzle et al. (" A Hysteresis-free platinum alloy flexure material for improved performance and reliability of MEMS devices").
- 5. Mayer discloses a stent made up of a platinum: iridium alloy having about 70%-80% platinum and 20%-30% iridium (paragraph 76). Mayer also discloses a 90% platinum 10% nickel alloy and a platinum tungsten alloy containing 5-15% tungsten. Mayer discloses the enhanced radiopacity of the stent because of these materials (abstract). Mayer further discloses that the stent may be balloon expandable or self-expandable as is well known in the art (paragraphs 5 and 28). Mayer also discloses the use of biocompatible coatings on the surface of the stent device (paragraph 27). Furthermore, Mayer discloses the use of a delivery catheter (paragraph 79) which encompasses balloon delivery catheters which are old and well known in the art for stent delivery as is there placement at the distal end of the catheter for deployment.

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Mayer teaches the invention as claimed and as discussed above. However,

Mayer does not disclose the use of an alloy made of about 75-80% platinum, 12-18% of
rhodium, and 5-10% or ruthenium.

Brazzle teaches the use of Alloy 851 (a trade name for a platinum alloy having 79% platinum, 15% rhodium, and 6% ruthenium) in MEMS (microelectromechanical systems) as an ideal spring material.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Mayer with the alloy taught by Brazzle in order to gain desirable properties such as biocompatibility and extreme corrosion resistance as taught by Brazzle (abstract).

- Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer 2003/0009215 in view of Brazzle et al. (" A Hysteresis-free platinum alloy flexure material for improved performance and reliability of MEMS devices"), as applied to Claim 1 above, and further in view of Alt 6.767.360.
- 7. Mayer in view of Brazzle teaches the invention as claimed and as discussed above. However, Mayer in view of Brazzle does not explicitly teach a stent having a sidewall thickness of less than 0.0035 inches.

Alt '360 teaches that a coronary stent has a sidewall thickness of 100 microns or less (col. 7, II. 50-55).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Mayer in view of Brazzle with the sidewall width of Alt

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'360 since this is the typical strut width of a coronary stent as taught by Alt (col. 7, II. 50-55).

- Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer 2003/0009215 in view of Brazzle et al. ("A Hysteresis-free platinum alloy flexure material for improved performance and reliability of MEMS devices"), as applied to Claim 10, further in view Alt 2004/0039438.
- Mayer in view of Brazzle teaches the invention as claimed and as discussed above. However, Mayer in view of Brazzle does not teach a stent having iridium oxide or titanium nitrate coatings as well as therapeutic coatings.

Alt '438 teaches a stent having a titanium nitrate or iridium oxide coating as well as therapeutic coatings (abstract) to inhibit tissue irritation and to deliver therapeutics to a local site in the body.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Mayer in view of Brazzle with the coatings of Alt '438 in order to prevent tissue irritation and deliver drugs locally in the body.

- Claims 40-42, 44, and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer 2003/0009215 in view of Speidel ("Resistance to fatigue crack growth of the platinum metals").
- 11. Mayer teaches the invention as claimed and as discussed above. However, Mayer does not teach a stent made of an alloy that has a composition of about 65%-75% of platinum and 25-35% of rhodium.

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Speidel teaches that a 70% platinum / 30% rhodium as a useful platinum alloy because rhodium has a higher resistance to fatigue crack growth than most other metals under cyclical stress (abstract).

It would have been obvious to modify the stent of Mayer with the alloy disclosed in Speidel in order to resist fatigue crack growth under cyclical loading as taught by Speidel (abstract) since it is known that stents undergo cyclical stress *in vivo* and manufacturers would be motivated to use alloys that would resist cracking.

- Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer
 2003/0009215 in view of Speidel ("Resistance to fatigue crack growth of the platinum metals") as applied to Claim 40, further in view of Alt 6,767,360.
- 13. Mayer in view of Speidel teaches the invention as claimed and as discussed above. However, Mayer in view of Speidel does not explicitly teach a stent having a sidewall thickness of less than 0.0035 inches.

Alt '360 teaches that a coronary stent has a sidewall thickness of 100 microns or less (col. 7, II. 50-55).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Mayer in view of Speidel with the sidewall width of Alt '360 since this is the typical strut width of a coronary stent as taught by Alt (col. 7, II. 50-55).

14. Claims 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer 2003/0009215 in view of Speidel ("Resistance to fatigue crack growth of the platinum metals") as applied to Claim 44, further in view Alt 2004/0039438.

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15. Mayer in view of Speidel teaches the invention as claimed and as discussed above. However, Mayer in view of Speidel does not teach a stent having iridium oxide or titanium nitrate coatings as well as therapeutic coatings.

Alt '438 teaches a stent having a titanium nitrate or iridium oxide coating as well as therapeutic coatings (abstract) to inhibit tissue irritation and to deliver therapeutics to a local site in the body.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Mayer in view of Speidel with the coatings of Alt '438 in order to prevent tissue irritation and deliver drugs locally in the body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON-DENNIS STEWART whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/ Primary Examiner, Art Unit 3774

/Jason-Dennis Stewart/ Examiner, Art Unit 3738